0170 '99 DEC 27 A8:32

NADA Approval date: NOV 3 1999

FREEDOM OF INFORMATION SUMMARY

Supplemental new animal drug application

NADA 140-976

Neomix® 325 Medicated Premix
Neomix® AG 325 Medicated Premix

Neomix® 325 and Neomix® AG 325 is indicated for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep and goats.

Sponsored by:

Pharmacia & UpJohn Company
Kalamazoo, Michigan 49001

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION

NADA Number:	140-976
Sponsor:	Pharmacia & UpJohn Company Kalamazoo, Michigan 4900 1
Generic Name:	Neomycin sulfate
Trade Name:	NEOMIX® 325 Medicated Premix NEOMIX® AG 325 Medicated Premix
Marketing Status:	OTC

2. **INDICATIONS FOR USE:** For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep and goats.

3. **A. DOSAGE FORM:** Type A Medicated Article

B. ROUTE OF ADMINISTRATION: Orally in feed or milk.

C. RECOMMENDED DOSAGE: The drug is administered at 10 mg neomycin sulfate per pound of body weight per day in divided doses for a maximum of 14 days.

4 **EFFECTIVENESS:** The drug was originally approved as safe for use as labeled on March 21, 1958. The drug was the subject of National Academy of Sciences/National Research Council (NAS/NRC) reports which were published in the FEDERAL REGISTER of January 19, 1971 (DESI 1 1-315V, 36 FR 837). The NAS/NRC evaluated the drug as "probably effective" for use in the control and treatment of bacterial enteritis in cattle, horses, sheep, swine, goats, cats, turkeys, chickens, ducks, and mink, and as a wet antibacterial dressing in swine, cattle, sheep, dogs. The NAS/NRC stated in relevant part: (1) the labeling should warn that treated animals must actually consume enough medicated feed or medicated water to provide a therapeutic dose under the conditions that prevail – as a precaution, the label should state the desired oral dose per unit of animal weight per day for each species as a guide to effective use of the preparation in drinking water or feed; (2) the labeling should warn that oral neomycin sulfate is not indicated if animals have developed a septicemia as systemic levels of neomycin are not obtained because of the low degree

of absorption from the gastrointestinal tract; (3) the disease claims for preparations administered orally must be restricted to disease involving the gastrointestinal tract because of the chemical and pharmacological properties of neomycin sulfate; and (4) each disease claim should be properly qualified as "appropriate for use in (name of disease) caused by pathogens sensitive to (name of drug)", and if the disease claim cannot be so qualified the claim must be dropped, (5) claims made regarding "for prevention of" or "to prevent " should be replaced with "as an aid in the control of" or " to aid in the control of" and (6) the recommended dosages are inconsistent.

The Food and Drug Administration concurred with the academy's findings, interpreting the phrase ". . .cannot be so qualified.. ." in paragraph (4) to mean" . . .is not supported by adequate data.. . ." (See 36 Fed. Reg. 837). FDA then proceeded to review all available data relating to the effectiveness of products subject to NADA 140-976 to determine which label claims were supported by the requisite proof of effectiveness. That review resulted in a letter dated December 10, 1985, addressed to the Animal Health Institute (AHI), in which the agency stated that it had "concluded that such data supported effectiveness for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle, (excluding veal calves) sheep, and goats, and swine."

Thereafter, the sponsor complied with the evaluation of NAS/NRC and FDA's conclusions in the following manner:

1. One disease of the gastrointestinal tract (colibacillosis in cattle, swine, sheep and goats) has been properly qualified as being caused by pathogens sensitive to neomycin sulfate. Disease claims which were not so qualified (including all claims involving use in poultry, horses, mink, dogs and cats) have been deleted from labeling.

2. The appropriate oral dose of 10 mg neomycin sulfate per unit of animal weight per day in each species has been incorporated in the labeling.

3. The revised labeling contains the statements that animals must have the medicated feed adjusted to compensate for variation in age and weight of the animal, the nature and severity of disease signs, and environmental temperature and humidify, each of which affects water consumption.

4. The labeling also contains a statement that the use of oral neomycin is not indicated as a sole treatment, if the animal develop septicemia.

5. The product is labeled for the treatment and control colibacillosis caused by *E. coli.*

5 ANIMAL SAFETY: The drug was originally approved as safe on March 2 1, 1958. No further safety data are required.

6 **HUMAN FOOD SAFETY:**

The NAS/NRC evaluation of the drug is concerned only with the effectiveness and safety of the drug for the treated animal. FDA's approval of the supplemental application did not involve reevaluation or reaffirmation of the human food safety data in the parent application.

Tolerance

A tolerance of 7.2 parts per million (ppm) is established for residues of parent neomycin (marker residue) in uncooked edible kidney (target tissue) in uncooked edible kidney (target tissue), 7.2 ppm in fat, 3.6 ppm in liver, 1.2 ppm in muscle of cattle, swine, sheep, and goats. A tolerance of 0.15 ppm is established for neomycin in milk.

Withdrawal periods: Cattle-l day, sheep-2 days, swine & goats- 3 days.

Regulatory Method for Residues

The regulatory analytical method for detection of residues of the drug is a microbiological test using Staphylococcus epidermis suspension. The method is as published by the Food and Drug Administration, "Antibiotic Residues in Milk, Dairy Products and Animal Tissues: Methods, Reports, and Protocols", revised October 1968, reprinted December 1974.

7 **AGENCY CONCLUSIONS:**

This supplemental NADA satisfies the requirements of section 5 12 of the Act and demonstrates that Neomycin Sulfate Type A Medicated Article, when used under its proposed conditions of use, is safe and effective for the labeled indications. The approval provides for use of Neomycin Sulfate Type A Medicated Article for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep and goats.

The "probably effective" finding of the NAS/NRC regarding neomycin sulfate which was published in the FEDERAL REGISTER of January 19, 1971, was subsequently reviewed by FDA, resulting in the December 10, 1985 letter to AH1 discussed above. , the "probably effective" status for neomycin sulfate medicated feed was upgraded to "effective" status with respect to the claims noted in the previous paragraph, The firm submitted revised labeling to conform to the letter to AH1 and, therefore, this supplemental NADA complies with the NAS/NRC evaluation and FDA's conclusions.

Neomycin sulfate medicated feed for use in food-producing animals is currently on the market as an over-the-counter product. The layman, and the conditions can

make accurate diagnosis with a reasonable degree of certainty for use described in the labeling are likely to be followed in practice. Therefore, the Center for Veterinary Medicine has concluded that this product should retain over-the-counter marketing status.

Under the Center's supplemental approval policy (21 CFR 5 14.106(b)(2)), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug and, therefore, did not require a reevaluation of the human food or target animal safety data in the parent application.

Under the Generic Animal Drug and Patent Term Restoration Act of 1988, this approval does not qualify for an exclusivity period under section 5 12(2)(F)(iii) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 360b(2)(F)(iii) because the supplemental application does not contain reports of new clinical or field investigations or human food safety studies (other that bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

Labels: (Attached)

Neomix® 325
Neomix® 325 Milk Replacer
Neomix AG® 325
Neomix AG® 325 Milk Replacer
Blue Bird Super Type B Feed
Blue Bird Super Type C Milk Replace
Blue Bird Super Type C Feed

cc: HFV- 199, NADA 140-976-E-0002
HFV-102 GADQC Reserve Copy
HFV-102 Green Book (N. Turner)
HFV-2, Special Mailing List
HFV-12 FOI Staff
HFV- 102 McRae ✓
HFR-MW250, DET-DO

DMcRae/imc final 11/2/99

ec: CVM Records\ONADE\\N140976\E0002FOI.SUM

NDC 0009-0553-XX

Neomix® 325

Medicated Premix
(Type A Medicated Article)

For use in the manufacture of medicated feeds

neomycin sulfate
(commercial grade)

Antibacterial

For the treatment and control of **colibacillosis** (bacterial enteritis) caused by ***Escherichia coli*** susceptible to **neomycin sulfate** in cattle, swine, sheep and goats.

Active ingredient:.....neomycin sulfate, 325 grams per pound
Inert ingredient:..... sucrose

Caution: For use in dry feeds only – not for use in liquid feed supplements

Restricted Drug- Use only as directed (California)

NADA 140876, Approved by FDA

Pharmacia & Upjohn

Net weight 50 lb (22.7 kg)

Neomix® 325

For use as a Type A medicated article in the preparation of Type B or Type C Medicated Feeds.

Dosage and administration: Administer IO mg neomycin sulfate per pound of body weight per day for a maximum of 14 days.

It is recommended that Neomix® 325 be diluted to prepare an intermediate or working premix prior to addition to final feed. Working premixes typically contain one part Neomix® 325 to 4 to 19 parts feed.

Type B Feeds:

Type B medicated feeds may contain 1.12 to 140 grams of Neomix® 325 per pound of medicated feed (to provide 0.8 to 100 grams of neomycin sulfate) per pound of Type B feed.

Type C Feeds:

Animai	Use Level
Cattle, swine, sheep or goats	Will vary depending on animal consumption and weight. Medicated feeds may contain 400-I 600 g/ton of neomycin sulfate in complete feed.

Caution: To provide IO mg per pound body weight per day, the concentration of neomycin sulfate required in medicated feed must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects feed consumption. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. If symptoms such as fever, depression or going off feed develop, oral neomycin sulfate is not indicated as the sole treatment since systemic levels of neomycin sulfate are not obtained due to low absorption from the gastrointestinal tract.

important: Treatment should continue for24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days for cattle, swine, sheep or goats.

Warning: Not for human use. Keep out of reach of children. Discontinue treatment prior to slaughter by at least the number of days listed below for appropriate species. .

Cattle.....1 day	Sheep..... .2 days
Swine.....3 days	Goats..... .3 days

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

A milk discard time has not been established for this product in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older, or female dairy goats 12 months of age or older.

Important: Store in a dry place. When storing partially used containers, securely close bags to prevent contents from caking.

Pharmacia & Upjohn
Kalamazoo, Ml 49001, USA

Lot Number:
Expiration:

NDC 0009-0553-XX

Neomix AG® 325

Medicated Premix
(Type A Medicated Article)

For use in the manufacture of medicated feeds

neomycin sulfate
(agricultural grade)

Antibacterial

For the treatment and control of **colibacillosis** (bacterial enteritis) caused by ***Escherichia coli*** susceptible to neomycin sulfate in cattle, swine, sheep and goats.

Active ingredient: . . . . . neomycin sulfate, 325 grams per pound
Inert ingredient:... . . . . sucrose

Caution: For use in dry feeds only – not for.use in liquid feed supplements

Restricted Drug- Use only as directed (California)

NADA 140-976, Approved by FDA

Pharmacia & Upjohn

Net weight 50 lb (22.7 kg)

Neomix AG® 325

For use as a Type A medicated article in the preparation of Type B or Type C Medicated Feeds,

Dosage and administration: Administer 10 mg neomycin sulfate per pound of body weight per day for a maximum of 14 days.

It is recommended that Neomix AG® 325 be diluted to prepare an intermediate or working premix prior to addition to final feed. Working premixes typically contain one part Neomix AG® 325 to 4 to 19 parts feed.

Type B Feeds:

Type B medicated feeds may contain 1.12 to 140 grams of Neomix AG® 325 per pound of medicated feed (to provide 0.8 to 100 grams of neomycin sulfate) per pound of Type B feed.

Type C Feeds:

Animal	Use Level
Cattle, swine, sheep or goats	Will vary depending on animal consumption and weight. Medicated feeds may contain 400-l 600 g/ton of neomycin sulfate in complete feed.

Caution: To provide 10 mg per pound body weight per day, the concentration of neomycin sulfate required in medicated feed must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects feed consumption. if symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. If symptoms such as fever, depression or going off feed develop, oral neomycin sulfate is not indicated as the sole treatment since systemic levels of neomycin sulfate are not obtained due to low absorption from the gastrointestinal tract. .

important: Treatment should continue for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of Idconsecutive days for cattle, swine, sheep or goats.

Warning: Not for human use. Keep put of reach of children. Discontinue treatment prior to slaughter by at least the number of days listed below for appropriate species.

Cattle.....I day	Sheep.. ..... .2 days
Swine.....3 days	Goats ..... .3 days

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

A milk discard time has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

important: Store in a dry place. When storing partially used containers, securely close bags to prevent contents from caking.

Pharmacia & Upjohn
Kalamazoo, Ml 49001, USA

Lot Number:
Expiration:

NDC 0009-0553-XX

Neomix® 325

Medicated Premix
(Type A Medicated Article)

For’use in the manufacture of medicated milk replacers

neomycin sulfate
(commercial grade)

Antibacterial

For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in calves, piglets, lambs and goat kids.

CT-

Active ingredient: . . . . . .neomycin sulfate, 325 grams per pound
Inert ingredient: . . . . . sucrose

Caution: For use in dry feeds only – not for use in liquid feed supplements

Restricted Drug- Use only as directed (California)

NADA 140-976, Approved by FDA

Pharmacia & Upjohn

Net weight 50 lb (22.7 kg)

Neomix® 325

Neomix® 325 medicated premix for use in milk replacers for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia co/i* susceptible to neomycin sulfate.

Directions for Use

Dose: 10 mg neomycin sulfate per pound body weight per day. Feed for not more than 14 days.

Mixing Directions

1000 grams per ton	1600 grams per ton
Mix 3.08 lb Neomix® 325 in 1 ton of milk replacer	Mix 4.92 lb Neomix® 325 in 1 ton of milk replacer

Example of Feeding Directions for Milk Replacers

Note that the examples are based on the following assumptions:
Young animals will consume milk replacer at 10% of their bodyweight per day.
Calf and kid milk replacers will contain 12.5% solids after reconstitution.
Lamb and piglet milk replacers will contain 20% solids after reconstitution.

Animal	Use level of neomycin sulfate	Pounds of Neomix ® 325/ton
Calf	10 mg/lb body weight daily	4.92[1]
Kid	10 mg/lb body weight daily	4.92[2]
Lamb	10 mg/lb body weight daily	3.08[3]
Piglet	10 mg/lb body weight daily	3.08[4]

[1]Calf weighing 100 lb. consuming 1.25 lb dry milk replacer mixed with 1.1 gallon (140 fluid ounces) of water.
[2]Kid weighing 20 lb. consuming 0.25 lb dry milk replacer mixed with 1.75 pints (28 fluid ounces) of water.
[3]Lamb weighing 20 lb. consuming 0.4 lb dry milk replacer mixed with 1.6 pints (26 fluid ounces) of water.
[4]Piglet weighing 10 lb. consuming 0.2 lb dry milk replacer mixed with 0.8 pints (13 fluid ounces) of water.

Caution: To administer 10 mg per pound body weight per day, the concentration of neomycin sulfate required in medicated milk replacer must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects feed consumption. if symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. if symptoms such as fever, depression or going off feed develop, oral neomycin sulfate is not indicated as the sole treatment since systemic levels of neomycin sulfate are not obtained due to low absorption from the gastrointestinal tract.

Important: Treatment should continue for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days for calves, piglets, lambs or kids.

Warning: Not for human use. Keep out of reach of children. Discontinue treatment prior to slaughter by at least the number of days listed below for appropriate species.

Ruminating Calves..... 1 day	Lambs..... .2 days
Piglets.. ..... .3 days	Kids.....3 days

A withdrawal period has not been.established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

A milk discard time has not been established for this product in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older, or female dairy goats 12 months of age or older.

Important: Store in a dry place. When storing partially used containers, securely close bags to prevent contents from caking.

Lot number:
Expiration:

Pharmacia & Upjohn
Kalamazoo, Ml 49001; USA

NDC 0009-0553-XX

Neomix AG® 325

Medicated Premix
(Type A Medicated Article)

For use in the manufacture of medicated milk replacers

neomycin sulfate
(agricultural grade)

Antibacterial

For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in calves, piglets, lambs and goat kids.

Active ingredient: ..... neomycin sulfate, 325 grams per pound
Inert ingredient: .....sucrose

Caution: For use in dry feeds only – not for use in liquid feed supplements

Restricted Drug- Use only as directed (California)

NADA 140-976, Approved by FDA

Pharmacia & Upjohn

Net weight 50 lb (22.7 kg)

Neomix AG® 325

Neomix AG" 325 medicated premix for use in milk replacers for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate.

Directions for Use

Dose: 10 mg neomycin sulfate per pound body weight per day. Feed for not more than 14 days.

Mixing Directions

1000 grams per ton	1600 grams per ton
Mix 3.08 lb Neomix® AG 325 in 1 ton of milk replacer	Mix 4.92 lb Neomix® AG 325 in 1 ton of milk replacer

Example of Feeding Directions for Milk Replacers

Note that the examples are based on the following assumptions:
Young animals will consume milk replacer at 10% of their bodyweight per day.
Calf and kid milk replacers will contain 12.5% solids after reconstitution.
Lamb and piglet milk replacers will contain 20% solids after reconstitution.

Animal	Use level of neomycin sulfate	Pounds of Neomix AG® 325/ton
Calf	10 mg/lb body weight daily	4.92[1]
Kid	IO mg/lb body weight daily	4.92[2]
Lamb	IO mg/lb body weight daily	3.08[3]
Piglet	10 mg/lb body weight daily	3.08[4]

[1]Calf weighing 100 lb. consuming 1.25 lb dry milk replacer mixed with 1.1 gallon (140 fluid ounces) of water.
[2]Kid weighing 20 lb. consuming 0.25 lb dry milk replacer mixed with 1.75 pints (28 fluid ounces) of water.
[3]Lamb weighing 20 lb. consuming 0.4 lb dry milk replacer mixed with 1.6 pints (26 fluid ounces) of water.
[4]Piglet weighing IO lb. consuming 0.2 lb dry milk replacer mixed with 0.8 pints (13 fluid ounces) of water.

Caution: To administer 10 mg per pound body weight per day, the concentration of neomycin sulfate required in medicated milk replacer must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects feed consumption. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. If symptoms such as fever, depression or going off feed develop, oral neomycin sulfate is not Indicated as the sole treatment since systemic levels of neomycin sulfate are not obtained due to low absorption from the gastrointestinal tract.

Important: Treatment should continue for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days for calves, piglets, lambs or kids.

Warning: Not for human use. Keep out of reach of children. Discontinue treatment prior to slaughter by at least the number of days listed below for appropriate species.

Ruminating Calves . . . . . 1 day	Lambs . . . . . 2 days
Piglets . . . . . 3 days	Kids . . . . . 3 days

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.,

A milk discard time has not been established for this product in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older, or female dairy goats 12 months of age or older.

Important: Store in a dry place. When storing partially used containers, securely close bags to prevent contents from caking.

Lot number:
Expiration:

Pharmacia & Upjohn
Kalamazoo, MI 49001, USA

BLUE BIRD SUPER TYPE B FEED

MEDICATED

For animals in the xxxxxx phase of growth

For-the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle, swine, sheep and goats.

Active Ingredients

Neomycin sulfate.....0.8 100 grams/lb

Guaranteed Analysis

Crude Protein (min %) .....
Lysine (min %, swine only) .....
Crude Fat (min %) .....
Crude Fiber (min %) .....
Calcium (min % for swine, for cattle, sheep and goats only if added) .....
Calcium (max % for swine, for cattle, sheep and goats only if added) .....
Phosphorus (min % for swine, for cattle, sheep and goats only if added) .....
Salt (min %, only if added) .....
Salt (max %, only if added) .....
Potassium (min % for cattle only if added) .....
Copper (min ppm, for sheep and goats if added) .....
Selenium (min ppm, for swine, for sheep and goats if added) .....
Zinc (min ppm, for swine) .....
Vitamin A (IU/lb, for cattle, sheep and goats if added) .....

Ingredient Statement

Ingredients as defined by AAFCO.

Directions for Use

Mix into feed at a level to provide 10 mg of neomycin sulfate per pound of body weight per day for 24 to 48 hours beyond the remission of symptoms, not to exceed 14 consecutive days.

Warning

Discontinue treatment at least 1 day prior to slaughter of cattle, 2 days prior to slaughter of sheep or goats, and 3 days prior to slaughter of pigs.

Iniportant

Treated animals must actually be consuming enough medicated feed to provide 10 mg neomycin sulfate per pound of body weight per day.

Caution

If symptoms persist after using this preparation for two to three days, the diagnosis should be redetermined. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

A milk discard time has not been established for this product in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older, or female dairy goats 12 months of age or older.

Manufactured By:
Blue Bird Feed Mill
City, State, Zip

NET WT 50 LB (22.67 kg)

BLUE BIRD SUPER TYPE C FEED

MEDICATED

For animals in the xxxxxx phase of growth

For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle, swine, sheep and goats.

Active Ingredients*

Neomycin sulfate.. ..... **

Guaranteed Analysis

Crude Protein (min %) .....
Lysine (min %, swine only) .....
Crude Fat (min %) .....
Crude Fiber (min%) .....
Calcium (min % for swine, for cattle, sheep and goats only if added) .....
Calcium (max % for swine, for cattle, sheep and goats only if added) .....
Phosphorus (min% for swine, for cattle, sheep and goats only if added) .....
Salt (min% , only if added) .....
Salt (max%, only if added) .....
Potassium (min% for cattle only if added) .....
Copper (min ppm, for sheep if added) .....
Selenium (min ppm, for swine, for sheep and goats if added) .....
Zinc (min ppm, for swine) .....
Vitamin A (IU/lb, for cattle, sheep and goats if added) .....

Ingredient Statement

Ingredients as defmed by AAFCO.

Direction2 for Use .

Mix into feed at a level to provide 10 mg of neomycin sulfate per pound of body weight per day for 24 to 48 hours beyond the remission of symptoms, not to exceed 14 consecutive days.

Warning

Discontinue treatment at least 1 day prior to slaughter of cattle, 2 days prior to slaughter of sheep or goats, and 3 days prior to slaughter of pigs.

Important

Treated animals must actually be consuming enough medicated feed to provide 10 mg neomycin sulfate per pound of body weight per day.

Caution

If symptoms persist after using this preparation for two to three days, the diagnosis should be redetermined. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

A milk discard time has not been established for this product in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older, or female dairy goats 12 months of age or older.

Manufactured By:
Blue Bird Feed Mill
City, State, Zip

NET WT SO LB (22.67 kg)

* Final printed label on formulated Type C Medicated feed must bear a single concentration.

** Concentration (grams per ton) must be such that the feed delivers 10 mg per pound of body weight per day based on body weight and feed consumption of animals and contain 400-1600 grams neomycin sulfate per ton.

BLUE BIRD SUPER TYPE C MILK REPLACER

MEDICATED

For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in calves, piglets, lambs and goat kids.

Active Ingredients

Neomycin sulfate..... *

Guaranteed Analysis .

Crude Protein (min %) .....
NPN (max %, goats and sheep only, if added) .....
Lysine (min %, swine only) .....
Crude Fat (min %) .....
Crude Fiber (max %) .....
Calcium (min %) .....
Calcium (max %) .....
Phosphorus (min %) .....
Salt (min %)** .....
Salt (max %)** .....
Sodium (min %)*** .....
Sodium (max %)*** .....
Copper (min ppm)**** .....
Selenium (min ppm) .....
Zinc (min ppm, swine only) .....
Vitamin A (IU/lb) .....

Ingredient Statement

Ingredients as defined by AAFCO.

Directions for Use

Feed reconstituted milk replacer at a level to provide 10 mg neomycin sulfate per pound of body weight per day as the sole ration for 24 to 48 hours beyond the remission of symptoms, not to exceed 14 consecutive days.

Warning

Discontinue treatment at least **1 day** prior to slaughter of calves, 2 days prior to slaughter of lambs or goat kids, and 3 days prior to slaughter of piglets.

Important

Treated animals must actually be consuming enough reconstituted milk replacer to provide 10 mg neomycin sulfate per pound of body weight per day.

Caution

If symptoms persist after using this preparation for two to three days, the diagnosis should be re-determined.
A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

A milk discard time has not been established for this product in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older, or female dairy goats 12 months of age or older.

Manufactured By:
Blue Bird Feed Mill
City, State, Zip

NET WT 50 LB (22.67 kg)

*Concentration (grams per ton) must be such that the milk replacer delivers 10 mg per pound of body weight per day based on body weight and milk replacer consumption of animals and contain 400-2000 grams neomycin sulfate per ton.
**Guaranteed required only when nutrient added except when the feed is intended, represented or serves as a principal source of the nutrient.
***Sodium guarantee required only when total sodium exceeds that furnished by the maximum salt guarantee.
****Copper guarantee for sheep required when added or level exceeds 20 ppm.